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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,767	11/16/2000	Dennis L. Bidney	35718/201902	5068

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/714,767	BIDNEY ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1,5,6 and 8-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 2-4 and 7 in Paper No. 10 is acknowledged.

Claims 1, 5-6, and 8-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11. Claims should be amended to delete nonelected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The abstract of the disclosure is objected to because it does not reflect the claimed invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 2-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn towards the sequences of an isolated nucleic acid having 60% sequence identity to SEQ ID NO: 3, or that hybridizes under stringent conditions to SEQ ID NO: 3, wherein said nucleic acid molecule encodes a polypeptide having LOX-like activity. Applicant further claims a DNA construct comprising said nucleic acid molecule operably linked to a promoter having 60% identity to SEQ ID NO: 5 or that hybridizes under stringent conditions to SEQ ID NO: 5.

Applicant describes a single LOX nucleic acid molecule (SEQ ID NO: 3).

Applicant does not describe the composition and structure of other DNA sequences with 60% identity to SEQ ID NO: 3, or that hybridize under stringent conditions to SEQ ID NO: 3 and encode LOX-like polypeptides. Further Applicant does not describe a nucleic acid molecule with promoter activity. Therefore, it is not clear that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

4. Claims 2-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the nucleotide sequence of Accession No. PTA-284, PTA-285, PTA-286, PTA-287, and PTA288 is required to practice the claimed invention. The specification does not provide a repeatable method for obtaining the nucleotide sequence of Accession No. PTA-284, PTA-285, PTA-286, PTA-287, and PTA288 and it does not appear to be readily available material. Without a publicly available deposit of the above, one of ordinary skill in the art could not be assured of the ability to make the invention in the same manner as claimed. Given the lack of guidance in the specification and inability of those in the art to reproduce specific DNA sequences, it would require undue experimentation for one skilled in the art to identify and obtain ^{the nucleotide sequences} ~~SEQ ID NO: 3~~. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of ^{the nucleotide sequences} ~~SEQ ID NO: 3~~. See 37 CFR 1.802.

Deposit of the nucleotide sequence of Accession No. PTA-284, PTA-285, PTA-286, PTA-287, and PTA288 would satisfy the enablement requirements of 35 U.S.C. 112, first

paragraph. Applicant indicates at page 11-12 of the specification that the nucleotide sequences were deposited at ATCC on June 30, 1999.

If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If the deposit was not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

(a) during the pendency of this application, access to the deposits will be afforded to one determined by the commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in the public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposits will be replaced if they should become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

5. Claims 2-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to the sunflower nucleic acid molecule of SEQ ID NO: 3, a DNA construct comprising said nucleic acid molecule operable linked to a promoter and a transformed host cell comprising said DNA construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are indefinite for the reasons discussed below. In particular, "stringent conditions" is indefinite and hence the claims read on any nucleic acid molecule encoding a polypeptide having LOX like activity operably linked to any promoter. Applicant also claims DNA constructs comprising said nucleic acid molecule operable linked to a promoter, particularly wherein said promoter is SEQ ID NO: 5 or SEQ ID NO: 10, and host cells comprising said DNA constructs.

Applicant teaches PCR based RACE isolation of a full length cDNA (SEQ ID NO: 3) from Sunflower by RNA profiling of *Sclerotinia* infected sunflower tissue, and teaches by BLAST analysis that the cDNA has sequence identity to a potato, tomato, rice, and *Arabidopsis* nucleic acid molecules that putatively encode lipoxygenase (LOX) (Example 1 page 57, lines 14-

23). Applicant teaches that Northern analysis of mRNA levels in sunflower tissue induced with Jasmonic acid or induced by wounding showed an increase in the steady state level of LOX mRNA (Example 2 page 61, lines 10-22 and pages 62-63 lines 25-31 and lines 1-4); Applicant provides general guidance for a method of transformation of immature maize embryo using *Agrobacterium* or a biolistic method (Example 3); a method of sunflower meristem explant transformation and regeneration using *Agrobacterium* or a biolistic method (Example 5); and a method of soybean somatic embryo transformation using *Agrobacterium* or a biolistic method (Example 6).

Applicant does not teach the enzymatic activity of the protein encoded by SEQ ID NO: 3. However, a database sequence search has revealed that the sequence shows a high level of sequence identity with confirmed potato (Royo *et al.* JBC, 271:21012-21019, 1996) and tomato (Parniske *et al.*, Cell, 91:821-832, 1997) nucleic acids. Further, Applicant does not teach the ability of SEQ ID NO:5 or SEQ ID NO: 10 to drive expression of an operably linked gene, and hence they are not enabled as a promoter per se. Finally, Applicant does not teach isolation of nucleic acid molecules with 60% sequence identity to SEQ ID NO: 3.

The inherent unpredictability in isolation of a nucleotide sequence encoding a LOX enzyme is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a range of enzymes involved in fatty acid metabolism (Broun *et al.* Science Vol. 282 13 November 1998; Abstract lines 4-6 and p. 1317 column 1, lines 51-56). Given that there is some degree of non specific binding in either PCR isolation of cDNA or probing cDNA libraries one

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of skill in the art would be required to screen through false positives to isolate the number of cDNA clones from the myriad of species commensurate with these claims. Further, the isolation of orthologous DNA sequences from other species introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable either PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited homology. Thus the screen for orthologous sequences would isolate many genes other than those of interest.

The isolation of orthologous cDNAs encoding a LOX enzyme and genomic DNA comprising DNA coding for LOX, an intron, and a putative LOX promoter 5' of the start site for translation would require making and testing of degenerate PCR primers and probes, as well as making and screening a multitude of cDNA and genomic libraries with those probes to isolate other LOX cDNA, genes and promoters. The testing of the putative positives would entail screening in transformed host cells, through a host of false positives to isolate other cDNAs encoding LOX and LOX promoter DNAs. Therefore undue experimentation would be required for one of skill in the art.

RE: Claim 4. Applicant is not enabled for all cells in vivo, including animal cells, and hence the claims should be limited to bacterial and plant cells, or host cells.

Given the lack of guidance, the absence of working examples in the specification that reflect the breadth of the claims, and the unpredictability in the art, undue trial and error would be needed to practice the invention. Therefore, the invention is not enabled throughout the broad scope of the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 2, lines 7-8 and in subsequent claims, "nucleotide sequence obtained from the overlapping clones" is indefinite. It is unclear what is encompassed by overlapping clones.

At Claim 2, lines 9-10 and in subsequent claims, "an antisense sequence corresponding to a sequence of b)" is indefinite. It is unclear if it refers to the nucleotide sequence or the amino acid sequence. Also, it is not clear what is intended by "corresponding to" in line 11.

At Claim 2, line 10, and in subsequent claims, "stringent conditions" is indefinite. It is unclear what the concentrations of salts or buffers used should be, or what temperature is intended in the hybridization and wash solutions. Hence, it is not clear what is encompassed by the claims.

At Claim 2, line 18, and in subsequent claims, "LOX-like activity" is indefinite". It is unclear whether the polypeptide has LOX activity or not.

Claim 2 recites the limitation "a nucleotide sequence obtained from the overlapping clones deposited in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "a nucleotide sequence obtained from the overlapping clones deposited in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rance *et al.* (PNAS, USA Vol. 95 pp. 6554-6559, May 1998).

The claims are indefinite for the reason discussed supra. . In particular, “hybridizes under stringent conditions” and “having LOX-like activity”, are indefinite and hence the claims read on essentially any LOX sequence, any promoter, and any transformed host cell.

Rance teaches a LOX gene, a promoter, and a transformed host cell (page 6555 column 2, lines 51-67).

Thus, the reference discloses the all the limitations of the instant claims 2-4 and 7.

10. All claims are rejected.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 308-0009.



Russell Kallis Ph.D.
July 16, 2002

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